

## **REMARKS**

Claims 1-13 are pending in the instant application. Claims 16-20 have been cancelled. Claims 14, 15, and 21-23 have been withdrawn. Claims 1 and 21 have been amended. The amendments to the claims merely bring the claims into accordance with the election following restriction requirement and do not constitute new matter. The rejections set forth in the Office Action are overcome by amendment or traversed by argument below.

### **1. Priority**

Applicants respectfully contend that the instant application is properly accorded priority to US provisional application S/N 60/254,649. The pending claims are directed toward SEQ ID NOs: 6 and 7. These sequences, while not specifically referred to as "SEQ ID NO: 6" or "SEQ ID NO: 7," were disclosed in the provisional application, contrary to the assertion of the Office Action. Applicants draw the attention of the Office to the following portions of US provisional application S/N 60/254,649: page 7, the legend for Figure 1 on page 34, and Figure 1 (in particular the shaded region, which corresponds to SEQ ID NOs: 6 and 7 of the instant application).

Thus applicants respectfully contend that the instant application is properly accorded a priority date of December 8, 2000, the filing date of US provisional application 60/254,649, and respectfully request the Office so assign this priority date.

### **2. Claim Objections**

(A) The Office Action has objected to Claim 1 under the assertion that it recited many sequences which were not elected by the Applicant in response to restriction requirement. In response, Applicants have amended this claim to recite only SEQ ID NO: 6, the elected sequence, and SEQ ID NO: 7, its complement, which, as the Office has acknowledged, is necessarily a part of a promoter consisting of SEQ ID NO: 6.

(B) The Office Action has objected to Claims 1-7 under the assertion that because Applicant elected SEQ ID NO: 6, the claims improperly recite one or more promoter sequences. Applicants respectfully traverse this objection.

As a first point, Applicants note that the claims necessarily include more than one promoter sequence, even in view of the election of SEQ ID NO: 6. The promoter, as the Office has

acknowledged, includes SEQ ID NO: 6 and therefore necessarily its complement SEQ ID NO: 7. In other words, the promoter necessarily includes the GPBP promoter sequence and the pol  $\kappa$  promoter sequence (one or more promoter sequences). Furthermore, as the Office Action has acknowledged in issuing its enablement rejection, vectors (and host cells containing those vectors) with one or more bidirectional promoters are encompassed within the claimed invention, and Applicants note that there is no restriction within the claim that the one or more promoters be *different* sequences. Therefore, the language of claims 1-7 remains appropriate even in view of the election of SEQ ID NO: 6.

Based on the above, Applicants respectfully request reconsideration and withdraw of the objections to claim 1-7.

### **3. Claim Rejections – 35 USC § 112, 2<sup>nd</sup> paragraph**

The Office Action has rejected Claims 1-13 and 16-19 under the assertion that they are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action asserts that Claim 1 encompasses only a single promoter sequence SEQ ID NO: 6 whereas the claims recite the use of one or more TNF inducible promoters. Applicants respectfully traverse these assertions.

Applicants first note that claims 16-19 have been cancelled, thus rendering their rejection moot. As noted above, there is no restriction within the claims that the one or more promoters be *different* sequences. Therefore, Applicants respectfully contend that the claims are not indefinite for reciting “one or more promoters” even in view of the sequence election. Thus Applicants respectfully request reconsideration and withdraw of the rejection of claims 1-13 as indefinite under 35 USC § 112, 2<sup>nd</sup> paragraph.

### **4. Claim Rejections – 35 USC § 112, 1<sup>st</sup> paragraph**

The Office Action has rejected Claims 2-13 under the assertion that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Specifically, the Office Action asserts that the specification, while being enabling for a single TNF inducible promoter to

induce gene expression, does not reasonably provide enablement for more than one TNF inducible promoters to induce expression. Applicants respectfully traverse these assertions.

Whether a specification is enabling is analyzed from the perspective of one of ordinary skill in the art. The preparation and use of constructs (and subsequent preparation of host cells, etc.) containing more than one promoter involves basic molecular biology techniques well within the purview of one of ordinary skill in the art. “A patent need not teach, and preferably omits, what is well known in the art.” MPEP 2164.01, citing *In re Buchner*, 929 F.2d 660,661 (Fed. Cir. 1991).

Additionally, Applicants respectfully contend that the Office has failed to follow its own Office guidelines: “[i]f a statement of utility in the specification contains within it a connotation of how to use... 35 U.S.C. 112 is satisfied.” MPEP 2164.01(c), citing *In re Johnson*, 282 F.2d 370, 373 (CCPA 1960), among others. The instant application discloses, for example, that constructs comprising one or more TNF inducible promoters may be used in identifying candidate compounds for treating or preventing autoimmune disorders or cancer, further noting such constructs can be used to distinguish between factors that might independently operate on one of the genes, and those that are involved in coordinate regulation of the various TNF-inducible genes (page 15, line 21 through page 16, line 29). Such a utility contains within it a connotation of how to use the constructs in accordance with Office guidelines for fulfilling the enablement requirement.

Furthermore, in issuing its rejection, the Office Action states that “the problem of predicting the gene expression of the multiple promoters is extremely complex, requiring trial and error experimentation.” Even assuming, *arguendo*, that this is true, it does not negate the fact that the specification is enabling for constructs having one or more promoters. “The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation.” MPEP 2164.01, citing *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165 (Int’l Trade Comm’n 1983).

Based on the above, Applicants respectfully contend that the specification is fully enabling for the pending claims, and respectfully request reconsideration and withdraw of the rejection of Claims 2-13 under the enablement requirement of 35 USC § 112, 1<sup>st</sup> paragraph.

**5. Rejoinder**

Applicants, believing that the elected product claims are allowable based upon the amendments and arguments presented herein, respectfully request rejoinder and examination of process Claims 14-15 and 21-23 in accordance with MPEP 821.04.

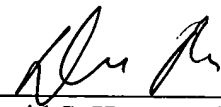
**CONCLUSIONS**

Applicants respectfully contend that all conditions of patentability are met for claims 1-13, 14-15, and 21-23 and therefore respectfully request allowance.

If the Examiner believes it to be helpful, the examiner is invited to contact the undersigned representative by telephone at (312) 913-2106.

Respectfully submitted,  
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